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May 18, 2005

The Office of Nutritional Products, Labeling, and Dietary Supplements  
Division of Nutrition Programs and Labeling (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**Title: New Product - Food Labeling; Notification Procedures for Statements on Dietary Supplements**

Dear Whom It May Concern:

We are going to launch a new product in June, 2005. We are going to sell it with three different product names (Osteo-D Flavone, IsoCal-D, or Flex-CID, please refer to the attached) through our two companies:

- Sedona Laboratories, Inc. (211 Jennifer Lane, Cottonwood, AZ 86326, 1-888-816-8804) will sell Osteo-D Flavone and IsoCal-D.
- Nutri-Health (218 Justin Drive, Cottonwood, AZ 86326, 1-800-914-6311) will sell Flex-CID.

The new product has the following ingredients:

- |  |                 |
|--|-----------------|
| 1. Isoflavone (sugar-free aglycone form) | 30 mg / tablet  |
| 2. Algal Calcium                         | 500 mg / tablet |
| 3. Vitamin D3 (cholecalciferol)          | 400 IU / tablet |

The main ingredients of the product are isoflavone and calcium. These two ingredients are widely used in the U. S. dietary supplements. Many published articles suggest that isoflavone might potentially confer health benefits related to osteoporosis, menopausal symptoms and cardiovascular disorder (please refer to the attached research articles). In addition, calcium and vitamin D supplementation are always necessary for bone health. Several risk factors are known in the pathogenesis of osteoporosis, first of all the lack of sufficient calcium and vitamin D intake, age, and genetic factors. Estrogen deficiency is the most likely cause of postmenopausal osteoporosis. Phytoestrogens are naturally occurring plant-derived phytochemicals, and have been shown to bind estrogen receptors and to behave as weak agonist/antagonist in both animals and humans. Phytoestrogens include mainly isoflavones. Isoflavone is known to be present in fruits, vegetables, and whole grains (mainly soybeans) commonly consumed by humans.

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**Sedona Labs, Inc.**

211 Jennifer Drive • Cottonwood, AZ 86326

tel: (888) 816-8804 • fax: (866) 887-8489

www.sedonalabs.com

**SEDONA LABS<sup>TM</sup>**

**The Digestive Health Specialists**

We are going to use sugar-free (aglycone) form of isoflavone and calcium from algae (seaweed). Since the aglycone form of isoflavone is a smaller molecule than sugar-bound (glycosidic) isoflavone, it is better absorbable. In addition, since algal calcium has a porous beehive structure (large surface area), this is better absorbable than other calcium. The high natural content of algae also helps calcium to be absorbed into the body. I attached some research data of algae calcium we are going to use.

Here is the list of the attached for more information.

1. The New Product Labels
2. Published Article about Isoflavone
3. Summary of Algal Calcium

I certify that all of the information and the attached data presented in this notice are accurate and truthful. If I can be of any assistance, please contact me at [mokang@sedonalabs.com](mailto:mokang@sedonalabs.com) or 1-800-914-6311.

Sincerely yours,



Mo Kang, MBA, MS

Senior Scientist

New Product Development Department

Sedona Laboratories, Inc.

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211 Jennifer Drive • Cottonwood, AZ 86326

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[www.sedonalabs.com](http://www.sedonalabs.com)

# 1. The New Product Labels

SUPPLEMENT FACTS		PROFESSIONAL USE ONLY	
Serving Size: 1 Tablet (600mg) Servings Per Container: 60		SEDONA LABS SINCE 1987	
Each Serving Contains:		A DIETARY SUPPLEMENT	
Isoflavone (aglycone) <sup>†</sup>	30 mg *	<b>Osteo-D Flavone™</b> A Highly Absorbable Form of Calcium, Isoflavone and Vitamin D 60 Tablets	
Algal Calcium <sup>†</sup>	500 mg 100%		
Vitamin D3 (cholecalciferol) <sup>†</sup>	400 IU 50%		
Other Ingredients: microcrystalline cellulose, hydroxypropyl methylcellulose *These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease. RexGene Biotech Co., LTD		<b>Osteo-D Flavone™</b> is a remarkable formulation for bone health and strength, containing a highly absorbable form of calcium with naturally occurring magnesium, that is 100% from algae sources, plus a non-soy, sugar-free form of isoflavone (aglycone). This product is not genetically modified. <b>Benefits:</b> May help maintain healthy bones and lipid levels for both men and women. May encourage and sustain both peri-menopausal and post-menopausal health.* Bottled in USA by: Sedona Labs 211 Jenner Lane, Cottonwood AZ 86326 888-816-8904 • www.sedonalabs.com ITEM: 700 6 48575 00204 5	

SUPPLEMENT FACTS		SEDONA LABS	
Serving Size: 1 Tablet (600mg) Servings Per Container: 60		A Dietary Supplement	
Each Serving Contains:		<b>IsoCal-D™</b> A Highly Absorbable Form of Calcium, Isoflavone & Vitamin D 60 Tablets	
Isoflavone (aglycone) <sup>†</sup>	30 mg *		
Algal Calcium <sup>†</sup>	500 mg 100%		
Vitamin D3 (cholecalciferol) <sup>†</sup>	400 IU 50%	<b>IsoCal-D™</b> is a remarkable formulation for bone health and strength, containing a highly absorbable form of calcium with naturally occurring magnesium, that is 100% from algae sources, plus a sugar-free, non-soy form of isoflavone (aglycone). This product is not genetically modified. <b>Benefits:</b> May help maintain healthy bones and lipid levels for both men and women. May encourage and sustain both peri-menopausal and post-menopausal health.* Manufactured for: Sedona Labs, Inc. 211 Jenner Lane, Cottonwood AZ 86326 888-816-8904 • www.sedonalabs.com ITEM: 21021 6 48575 21021 1	

NUTRI		HEALTH	
A DIETARY SUPPLEMENT		SUPPLEMENT	
<b>SUPPLEMENT FACTS</b> Serving Size: 1 Tablet (600mg) Servings Per Container: 60 Each Serving Contains: Isoflavone (aglycone) <sup>†</sup> 30 mg * Algal Calcium <sup>†</sup> 500 mg 100% Vitamin D3 (cholecalciferol) <sup>†</sup> 400 IU 50% Other Ingredients: microcrystalline cellulose, hydroxypropyl methylcellulose *These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease. ITEM: 077 6 48575 00010 2 Not affiliated with NutriHealth USA, LLC RexGene Biotech Co., LTD		<b>Flex-CID™</b> A Highly Absorbable Form of Calcium, Isoflavone and Vitamin D 60 Tablets <b>Flex-CID™</b> is a remarkable formulation for bone health and strength, containing a highly absorbable form of calcium with naturally occurring magnesium, that is 100% from algae sources, plus a sugar-free, non-soy form of isoflavone (aglycone). This product is not genetically modified. <b>Benefits:</b> May help maintain healthy bones and lipid levels for both men and women. May encourage and sustain both peri-menopausal and post-menopausal health.* <b>Suggested Use:</b> Take 2 tablets daily with meals, 1 with breakfast and 1 with dinner. If pregnant, consult physician before taking. Manufactured for: NUTRI-HEALTH 219 Junin Drive, Cottonwood AZ 86326 800-814-6511 • www.bestflora.com	